

## REMARKS

After entry of this Amendment, the pending claims are: claims 33-80. The Notice of Non-Compliant Amendment dated August 8, 2007, the Notice of Non-Compliant Amendment dated May 14, 2007 and the Office Action dated February 8, 2007 have been carefully considered. Claims 1-32 were previously canceled without prejudice. Claims 81-91 were previously canceled as being directed to a non-elected invention. The Applicants explicitly reserved the right to file continuation and/or divisional applications directed towards the embodiments of claims 81-91. Claims 37-42, 54-59, 62, 63, and 65-68 were previously withdrawn as being directed to non-elected species based on the understanding that the claims would only be restricted to the elected species if no generic claim is held allowable. Claims 33, 51, and 60 have been amended. No new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following Remarks is respectfully requested.

In the Notice of Non-Compliant Amendment dated August 8, 2007, the Examiner

- rejected the incorporation of the new limitations into independent claims 33 and 60 as being directed to a non-elected species; and
- rejected the Amendment filed on May 15, 2007 for failing to specifically point out support in the original disclosure for each newly presented claim limitation.

In the Notice of Non-Compliant Amendment dated May 14, 2007, the Examiner

- rejected the Amendment filed on May 7, 2007 for containing an incomplete listing of claims. In particular, the Examiner rejected the Amendment for failing to mention the status of claims 1-32. The listing of claims has hereby been amended to shown that claims 1-32 were previously canceled.

In the Office Action dated February 8, 2007, the Examiner:

- objected to the drawings as failing to comply with 37 CFR 1.84(p)(5)
- rejected claim 51 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention;
- rejected claims 33-36, 48, 49, 60, 61, 64, 74 and 75 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,496,318 to Howland *et al.* (“Howland”);
- rejected claims 33-36, 48-51, 60, 61, 71, 72, and 74-77 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,524,341 to Lang *et al.* (“Lang”);
- rejected claims 44, 70, and 78 under 35 U.S.C. 103(a) as being unpatentable over Lang in view of U.S. Patent No. 6,660,037 to Boyer *et al.* (“Boyer”);
- rejected claims 43 and 69 under 35 U.S.C. 103(a) as being unpatentable over Lang in view of U.S. Patent No. 4,932,975 to Main *et al.* (“Main”);
- rejected claims 47 and 73 under 35 U.S.C. 103(a) as being unpatentable over Lang in view of PCT Published Application No. WO 95/31158 to Taylor (“Taylor”); and
- rejected claims 52, 53, 79 and 80 under 35 U.S.C. 103(a) as being unpatentable over Lang.

## **NON-ELECTED SPECIES**

In the Notice of Non-Compliant Amendment dated August 8, 2007, the Examiner rejected the incorporation of the limitation into independent claims 33 and 60 requiring that the coupling portion is sized and configured to be elastically deformable as being directed to a non-elected species.

It is respectfully submitted that the concept of an elastically deformable coupling portion is disclosed at least in paragraphs [0013] to [0015] which are generally directed to all of the figures including Figs. 1A and 1B.

It is also respectfully submitted that the Examiner's position that the coupling portion is elastically deformable only applies to the species shown in Fig. 4 is without merit. It is respectfully submitted that the species shown in Fig. 4 is substantially identical to the species shown in Figs. 1A and 1B except that the species shown in Fig. 4 includes a locking bolt 28 which includes elastically deformable cams 31 so that the elastically deformable cams 31, and hence the locking bolt 28, can be secured to the eccentric relief 30. It is respectfully submitted that independent claims 30 and 66 have been amended to include the concept that the coupling portions of the first and second halves are elastically deformable, not the coupling means/locking feature as interpreted by the Examiner.

As such, it is respectfully submitted that the newly added claim limitation requiring that the coupling portion is sized and configured to be elastically deformable is directed to the elected species as shown in Fig. 1. Withdrawal of this rejection is respectfully requested.

#### **SUPPORT FOR NEW LIMITATIONS**

In the Notice of Non-Compliant Amendment dated August 8, 2007, the Examiner rejected the Amendment filed on May 15, 2007 for failing to specifically point out support in the original disclosure for each newly presented claim limitation.

It is respectfully submitted that independent claim 33 has been amended to require a prosthesis for implantation between a first spinous process and a second spinal process, the prosthesis comprising first and second halves each comprising a process portion, each process portion being sized and configured to be placed on either side of the first and second spinous processes and a coupling portion, each coupling portion having an axis and configured for insertion between the first and second spinous processes. It is respectfully submitted that support for this limitation can be found at least in paragraphs [0001] and [0005]-[0007].

Independent claim 33 has been further amended to require that the coupling portions are sized and configured to be elastically deformable. It is respectfully submitted that support for this limitation can be found at least in paragraphs [0013] to [0015].

It is respectfully submitted that independent claim 60 has been amended to require an interspinal prosthesis for implantation between a first spinous process and a second spinal process, the prosthesis comprising a first half comprising a coupling portion and a process portion, the coupling portion having a bore and configured for insertion into the interspinal space between the first spinous process and the second spinal process, the process portion being sized and configured to be placed on one side of the first and second spinous processes and being sized and configured to prevent its advancement into the interspinal space; a second half comprising a coupling portion and a process portion, the coupling portion configured to be received within the bore of the coupling portion of the first half, the process portion being sized and configured to be placed on the other side of the first and second spinous processes and being sized and configured to prevent advancement into the interspinal space. It is

respectfully submitted that support for this limitation can be found at least in paragraphs [0001] and [0005]-[0007].

Independent claim 60 has been further amended to require that the coupling portion of the first and second halves are sized and configured to be elastically deformable. It is respectfully submitted that support for this limitation can be found at least in paragraphs [0013] to [0015].

Independent claim 60 has been further amended to require that the coupling portion in the area between the first and second spinous processes has an unstressed diameter and a deformed diameter, said deformed diameter being between about 10% to about 50% of the unstressed diameter. It is respectfully submitted that support for this limitation can be found in originally filed dependent claim 5, which recited “[t]he prosthesis (1) of claims 1 to 4, characterized in that it is produced from an elastic material, which permits an elastic deformation of the diameter of the central part (2) at its narrowest place (10) of 10 to 50% and preferably 15 to 50% relative to the unstressed diameter.”

It is respectfully submitted that paragraph [0013] has also been amended to recite this language.

As such, it is respectfully submitted that proper support exists for all newly filed claim limitations. Withdrawal of this rejection is respectfully requested.

## **DRAWINGS**

Drawings were objected to for failing to comply with 37 CFR 1.84(p)(5). In particular, Fig. 1b was objected to for incorporating reference character “9” which is not mentioned in the specification. Reference character “9” has been deleted from Fig. 1b. Withdrawal of this objection is respectfully requested. Replacement Sheets (sheets 1-5) are attached hereto as Attachment A.

## **DEPENDENT CLAIM 51**

Dependent claim 51 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, dependent claim 51 was rejected for failing to provide sufficient antecedent basis for “the projection.” Dependent claim 51 has been amended to depend from claim 34. It is respectfully submitted that sufficient antecedent basis now exists for “the projection.” Withdrawal of this rejection is respectfully requested.

## **INDEPENDENT CLAIM 33**

Independent claim 33 was rejected under 35 U.S.C. 102(b) as being anticipated by Howland. In addition, independent claim 33 was rejected under 35 U.S.C. 102(b) as being anticipated by Lang.

As an initial matter, independent claim 33 has been amended without prejudice to make explicit what was already implicit. That is, independent claim 33 has been amended to require, *inter alia*, a prosthesis for implantation between a first spinous process and a second spinal process, the prosthesis

comprising first and second halves each comprising a process portion, each process portion being sized and configured to be placed on either side of the first and second spinous processes and a coupling portion, each coupling portion having an axis and configured for insertion between the first and second spinous processes. It is respectfully submitted that Lang is directed to an intervertebral spacer that is sized and configured to be located in between the endplates of adjacent vertebral. Thus, Lang does not disclose, teach or suggest a prosthesis for implantation between a first spinous process and a second spinal process wherein the prosthesis includes a process portion for placement on either side of the first and second spinous processes and a coupling portion for insertion between the first and second spinous processes. Thus, it is respectfully submitted that Lang does not disclose, teach or suggest all of the limitations of independent claim 33. Thus, it is respectfully submitted that independent claim 33 is allowable over the cited prior art. Withdrawal of this rejection is respectfully requested.

Independent claim 33 was rejected under 35 U.S.C. 102(b) as being anticipated by Howland. As amended, independent claim 33 requires, *inter alia*, a prosthesis for implantation between a first spinous process and a second spinal process, the prosthesis comprising first and second halves each comprising a process portion, each process portion being sized and configured to be placed on either side of the first and second spinous processes and a coupling portion, each coupling portion configured for insertion between the first and second spinous processes, the coupling portions being sized and configured to be elastically deformable. It is respectfully submitted that Howland does not disclose, teach or suggest an elastically deformable coupling portion.

Howland discloses a spinal fixation device 10 for insertion between the spinous processes of adjacent vertebrae wherein the spinal fixation device is sized and configured to be inserted in-between square notches 12 that are formed in the spinous processes of the adjacent vertebra so that when the spinal fixation device 10 is forced into the square notches, the spinous processes are forced apart and thereby apply a force to the anterior side of the vertebra, closing the gap between the adjacent vertebrae and adding to the distraction of the spinal column in this region. In order to accomplish this, the spinal fixation device 10 includes a plate 14 having an narrower end 15 and a rectangular shaped slot 18, a bar 16, a sliding bar 20 which includes a rectangular-shaped hollow section 21 for receiving the plate 14 and a pin 22. In use, the narrower end 15 of the spinal fixation device 10 is inserted into the space between the facing square notches in the adjacent vertebrae until the bar 16 abuts the side of the spinous processes, the gradually increasing width and depth of the plate gently forces the spinous processes apart. Thereafter, the sliding bar 20 is pushed onto the plate 14 and past the rectangular shaped slot 18 so that the slot 18 is exposed. The pin 22 is then inserted into the slot 18, thus holding the sliding bar 20 in place on the plate 14 and the plate 14 in place on the vertebrae. The components of the spinal fixation device are preferably made from ultra high density polyethylene (UHDP).

It is respectfully submitted that Howland does not disclose, teach or suggest a prosthesis for implantation between a first spinous process and a second spinal process, the prosthesis comprising first and second halves each comprising a coupling portion for insertion between the first and second spinous processes, wherein the coupling portions are sized and configured to be elastically deformable.



Therefore, it is respectfully submitted Howland does not disclose, teach, or suggest all of the limitations of independent claim 33. Withdrawal of this rejection and allowance of independent claim 33 is respectfully requested.

With respect to dependent claim 43 which was rejected under 35 U.S.C. 103(a) as being unpatentable over Lang in view of Main, it is respectfully submitted that Main was cited for the proposition that elastomeric material could be used with plate members to provide a cushioning effect. It is respectfully submitted that Main does not overcome the shortcomings of Lang described above. Thus, for at least this reason, withdrawal of this rejection is respectfully requested.

With respect to dependent claim 44 which was rejected under 35 U.S.C. 103(a) as being unpatentable over Lang in view of Boyer, it is respectfully submitted that Boyer was cited for the proposition that the implant could be made from metal. It is respectfully submitted that Boyer does not overcome the shortcomings of Lang described above. Thus, for at least this reason, withdrawal of this rejection is respectfully requested.

With respect to dependent claim 47 which was rejected under 35 U.S.C. 103(a) as being unpatentable over Lang in view of Taylor, it is respectfully submitted that Taylor was cited for the proposition that a hydroxyapatite coating could be used on the exterior surface of the process portions. It is respectfully submitted that Taylor does not overcome the shortcomings of Lang described above. Thus, for at least this reason, withdrawal of this rejection is respectfully requested.

Claims 34-36 and 43-53 all depend from independent claim 33, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 34-36 and 43-53 is also respectfully requested.

Moreover, claims 37-42 and 54-59 were withdrawn as being directed to a non-elected species. It is respectfully submitted that independent claim 33 is generic and, as such, claims 37-42 and 54-59 should be allowed as well.

### **INDEPENDENT CLAIM 60**

Independent claim 60 was rejected under 35 U.S.C. 102(b) as being anticipated by Howland. In addition, independent claim 60 was rejected under 35 U.S.C. 102(b) as being anticipated by Lang.

As an initial matter, independent claim 60 has been amended without prejudice to make explicit what was already implicit. That is, independent claim 60 has been amended to require, *inter alia*, an interspinal prosthesis for implantation between a first spinous process and a second spinal process, the prosthesis comprising a first half comprising a coupling portion and a process portion, the coupling portion having a bore and configured for insertion into the interspinal space between the first spinous process and the second spinal process, the process portion being sized and configured to be placed on one side of the first and second spinous processes; a second half comprising a coupling portion and a process portion, the coupling portion configured to be received within the bore of the coupling portion of the first half, the process portion being sized and configured to be placed on the other side of the first and second spinous processes. It is respectfully submitted that Lang is directed to an intervertebral

spacer that is sized and configured to be located in between the endplates of adjacent vertebral. Thus, Lang does not disclose, teach or suggest a prosthesis for implantation between a first spinous process and a second spinal process wherein the prosthesis includes a process portion for placement on either side of the first and second spinous processes and a coupling portion for insertion between the first and second spinous processes. Thus, it is respectfully submitted that Lang does not disclose, teach or suggest all of the limitations of independent claim 60. Thus, it is respectfully submitted that independent claim 60 is allowable over the cited prior art. Withdrawal of this rejection is respectfully requested.

Independent claim 60 was rejected under 35 U.S.C. 102(b) as being anticipated by Howland. As amended, independent claim 60 requires, *inter alia*, an interspinal prosthesis for implantation between a first spinous process and a second spinal process, the prosthesis comprising a first half comprising a coupling portion and a process portion, the coupling portion having a bore and configured for insertion into the interspinal space between the first spinous process and the second spinal process, the process portion being sized and configured to be placed on one side of the first and second spinous processes; a second half comprising a coupling portion and a process portion, the coupling portion configured to be received within the bore of the coupling portion of the first half, the process portion being sized and configured to be placed on the other side of the first and second spinous processes; wherein the coupling portion of the first and second halves are sized and configured to be elastically deformable such that the coupling portion in the area between the first and second spinous processes has an unstressed diameter and a deformed diameter, said deformed diameter being between about 10% to about 50% of the unstressed diameter.

It is respectfully submitted that support for such claim amendment is found in originally filed dependent claim 5 which read “[t]he prosthesis (1) of claims 1 to 3, characterized in that it is produced from an elastic material, which permits an elastic deformation of the diameter of the central part (2) at its narrowest place (10) of 10 to 50% ...”

As previously described in connection with independent claim 33 above, it is respectfully submitted that Howland does not disclose, teach or suggest an elastically deformable coupling portion and certainly does not disclose, teach or suggest an elastically deformable coupling portion such that the coupling portion in the area between the first and second spinous processes has an unstressed diameter and a deformed diameter, said deformed diameter being between about 10% to about 50% of the unstressed diameter. Thus, it is respectfully submitted that Howland does not disclose, teach, or suggest all of the limitations of independent claim 60. Withdrawal of this rejection and allowance of independent claim 60 is respectfully requested.

With respect to dependent claim 69 which was rejected under 35 U.S.C. 103(a) as being unpatentable over Lang in view of Main, it is respectfully submitted that Main was cited for the proposition that elastomeric material could be used with plate members to provide a cushioning effect. It is respectfully submitted that Main does not overcome the shortcomings of Lang described above. Thus, for at least this reason, withdrawal of this rejection is respectfully requested.

With respect to dependent claim 73 which was rejected under 35 U.S.C. 103(a) as being unpatentable over Lang in view of Taylor, it is respectfully submitted that Taylor was cited for the proposition that a hydroxyapatite coating could be used on the exterior surface of the process portions.

It is respectfully submitted that Taylor does not overcome the shortcomings of Lang described above. Thus, for at least this reason, withdrawal of this rejection is respectfully requested.

With respect to dependent claims 70 and 78 which were rejected under 35 U.S.C. 103(a) as being unpatentable over Lang in view of Boyer, it is respectfully submitted that Boyer was cited for the proposition that the implant could be made from metal. In addition, Boyer was cited for the proposition that the dimensions between the process portions or plates could be 14 mm. It is respectfully submitted that Boyer does not overcome the shortcomings of Lang described above. Thus, for at least this reason, withdrawal of this rejection is respectfully requested.

Claims 61, 64, and 69-80 all depend from independent claim 60, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 61, 64, and 69-80 is also respectfully requested.

Moreover, claims 62, 63, and 65-68, were withdrawn as being directed to a non-elected species. It is respectfully submitted that independent claim 60 is generic and, as such, claims 62, 63, and 65-68 should be allowed as well.

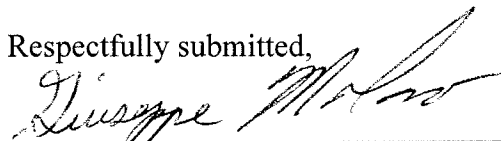
### CONCLUSION

No fee is believed due for this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

Date: September 5, 2007

Respectfully submitted,



Giuseppe Molaro  
Registration No. 52,039

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For: Brian M. Rothery  
Registration No. 35,340

Attorney for Applicants  
Stroock & Stroock & Lavan LLP  
180 Maiden Lane  
New York, New York 10038  
(212) 806-6114

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Attachment A

(Drawings: Replacement Sheets)